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Guidance criteria for management of medical devices in the National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway (Nye metoder)

Purpose

This document presents criteria for use in the National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway, "*Nye metoder*" for considering which medical devices to prioritize for evaluation using Health Technology Assessments (HTA). The criteria were developed to support the specialist health services, patients, industry and other stakeholders in preparing proposals of medical devices that should undergo an HTA in *Nye metoder*. The criteria may also lend support to several additional activities within *Nye metoder* including generating horizon scanning reports and suitability assessments by the Norwegian Institute of Public Health, prioritizing requests for HTA reports at a national level by the Commissioning Forum (*Bestillerforum RHF*), and in processes at hospitals for prioritizing mini-HTAs at the local level.

Background

Because the product range for medical devices is broad HTAs may not be relevant for all medical devices. These guidance criteria discuss managing medical devices in *Nye metoder*. Health technologies not covered by the guideline criteria may be subject to other procedures beyond the scope of *Nye metoder*.

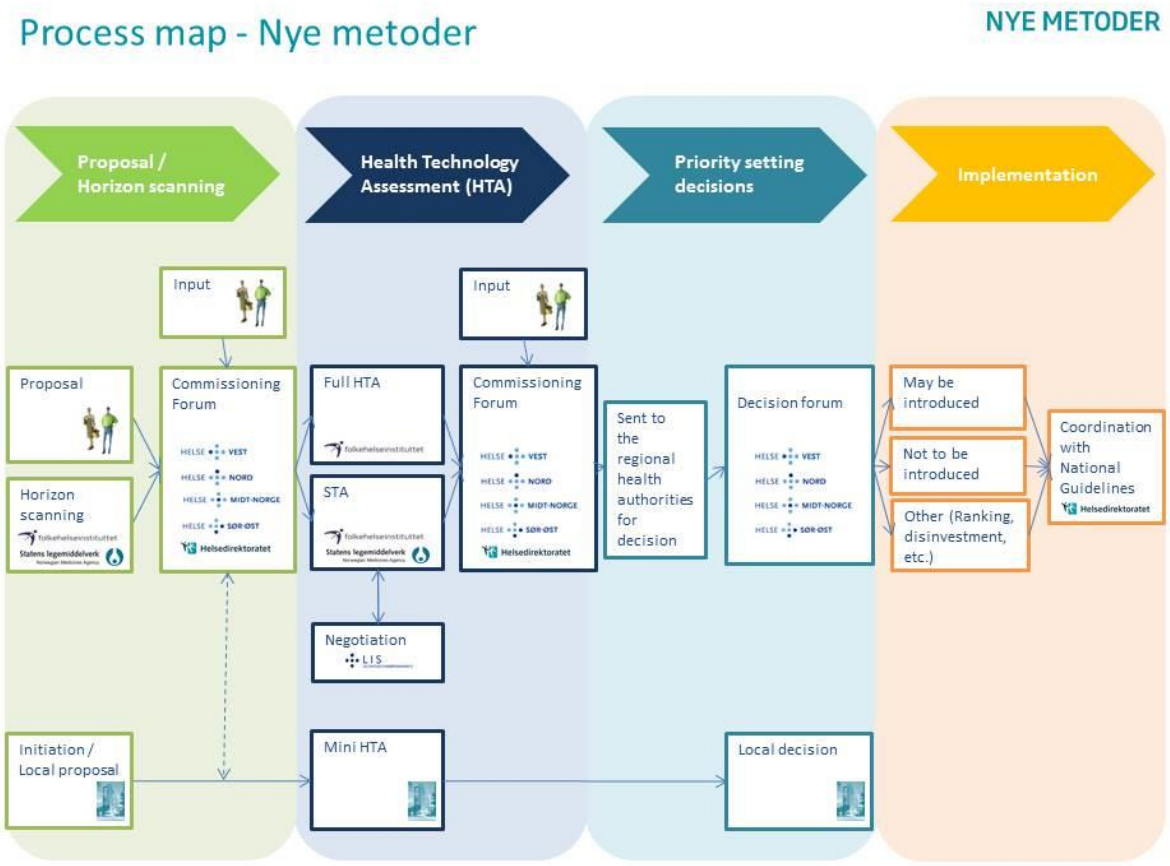
In 2015, *Nye metoder* established a working group to consider how new medical devices should be managed within the system. The group consisted of representatives of stakeholders in the system and external collaboration partners, with its secretariat located at the Norwegian Knowledge Centre for Health Services/Norwegian Institute of Public Health. The working group's output provides the context for these guidelines.

On the 12th December 2016, the Commissioning Forum issued its approval of the guidance criteria for handling medical devices in *Nye metoder*, and emphasized that individual cases must be assessed in context with reference to these criteria. For more information, see Annex 1.

Guidance criteria for medical devices in *Nye metoder*

It will be useful to examine the criteria for handling medical devices in relation to the process map for the system (figure 1). The criteria for medical devices must always be viewed in context, and can be divided into three steps. Step 1 consists of selection criteria, step 2 of relevance criteria and step 3 of level criteria. Some of the criteria will overlap and be included in different phases of the process that culminates in an overall assessment by the Commissioning Forum (or potentially a Health Authority) of whether to initiate an HTA.

Figure I – Process map for Nye metoder:



a) Selection criteria

The selection criteria provide guidance for a preliminary sorting mechanism to determine whether a specific medical device falls within the scope of *Nye metoder*, and can be subject to a horizon scanning report or proposal for HTA.

Table 1

Selection criteria:	*Yes*	*No*	*Not sure*	*Comments*
Is the technology relevant for use in the specialist health services?[1]				
Is this a new and innovative technology[2]?				

[1] *Nye metoder* applies primarily to the introduction of technologies in the specialist health service, which makes it relevant to determine in the first instance whether the technology is relevant for use in the specialist health service. Are there reasonable grounds to assume that the specialist health service will be responsible for initiating, evaluating and/or concluding patient care and/or investigation linked to use of the technology?

[2] InnoMed's definition of innovation (InnoMeds Strategi 2012-2013) is often used: "Innovation is a new product, a new service, a new production process or new organisational structure that is adopted and creates value, such as higher quality, increased effectiveness, better productivity in the health and care sector and increased satisfaction among patients, their relatives and staff." A technology that contributes to higher quality might be one that, compared with present practice, is more effective and/or safer, meets an unmet need, is more user-friendly or improves the working environment.

Is the technology relevant for disinvestment[3]?				
Is the technology CE-marked[4] or expected to be CE-marked soon as a medical device or in-vitro diagnostic?				
Will the specialist health services be potentially responsible for financing the technology?				
Is sufficient documentation on the technology available to allow an HTA to be performed?				

b) Relevance criteria

Relevance criteria help to characterize and elaborate the relevance of performing an HTA, and should be based on an overall assessment. Relevance criteria may support the process of horizon scanning and conduct of suitability assessments[5]. Additional comments on the current method/health technology related to the defined criteria are desirable here; however specific estimates are not expected at this stage (see Table II). Input concerning the general priority setting criteria in the health service[6] may be illustrated in a generalized way in the relevance assessment. The health technology's defined risk class can be used to assess whether the technology has a high risk level[7].

Table II

Relevance criteria:	*Yes*	*No*	*Not sure*	*Comments*
Is the technology designed for treating or investigating severe illnesses?				
Does the technology have large potential benefit?				
Is there a need for the technology[8]?				
Does the technology reflect a high degree of innovation[9]?				
Is there high risk associated with the technology? State the risk class[10] if possible.				
Will the technology have major budgetary implications for the specialist health service?				
Is there adequate documentation available (at least one clinical study measuring critical outcomes)? Are there any previous HTAs that could be used?				
Does the technology involve medical radiation?				

[3] Where it may be relevant to perform an HTA with a view to disinvestment of existing technology in the specialist health service, this must be indicated here.

[4] The manufacturer is responsible for documenting that the fundamental requirements in the regulations are met before a medical device is marketed. This is called a conformity assessment. Devices that meet the requirements are CE-marked as evidence that a conformity assessment has been performed (https://helsedirektoratet.no/medisinsk- utstyr/markedsforing-av-medisinsk-utstyr).

[5] A suitability assessment is a final check prior to a decision to initiate an HTA at national level. One important purpose is to assess the availability and scope of the underlying documentation as a basis for an HTA.

[6] Norwegian White Paper, 34 (2015-2016), Verdier i pasientens helsetjeneste – Melding om prioritering

[7] New Health Technologies: Managing Access, Value and Sustainability, OECD 2017

[8] The need for the technology should be clarified with relevant stakeholders in the specialist health service

[9] The degree of innovation should also be included in the assessment and will expand on the corresponding selection criteria by predicting relevance more clearly

[10] The risk classification of a medical device specifies which assessment procedure is to be utilised before the device is marketed. Please see Annex 2 for the contents of the risk classification (https://helsedirektoratet.no/medisinsk-utstyr/klassifisering-av-medisinsk-utstyr source)

c) Level criteria

Level criteria help to clarify whether the technology should be assessed through an HTA at the national level[11], a mini-HTA at the local level[12], or potentially not assessed with an HTA. The criteria must be viewed in context. The level criteria are used in the Commissioning Forum (national HTAs) and in the health authorities (mini-HTAs).

Table III

Level criteria for HTAs at national level:	*Yes*	*No*	*Not sure*	*Comments*
Does the technology have potentially major consequences for the specialist health service (for patient care, budget implications, organisation of services, etc.)?				
Is there high risk associated with the technology, e.g. implantable devices, and certain devices in risk class 3 and certain devices on list A (IVD)?[13]				
Will the technology be included in a national screening programme?				
Are national healthcare services "*Nasjonal behandlingstjeneste*" or options involving the technology being applied for?				
Is a comprehensive health-economic analysis (e.g. a cost-effectiveness analysis) of the technology required?				
Do pharmaceutical agents constitute a significant component of the technology?[14]				
Is the technology a diagnostic test that is crucial for the use of a pharmaceutical agent (companion diagnostic)[15]?				

Medical devices that do not fall under the national criteria in Table III can be assessed for a mini-HTA. Mini-HTAs are conducted, as required, at the hospital level. More information about mini-HTAs is available on the Norwegian Institute of Public Health's website[16].

Implementation of the guidance criteria

All health technologies that meet the guidance selection, relevance and level criteria may be relevant for an HTA at national level. Technologies that do not meet the level criteria may be relevant for a mini-HTA. The criteria must be assessed in a comprehensive context.

[11] An HTA at national level is initiated following a decision in the Commissioning Forum. This may derive from a proposal submitted to *Nye metoder* or HTAs generated from the national HTA function.

[12] Technology assessments at the local level consist of Hospital Based Health Technology Assessment (mini-HTAs) initiated based on circumstances at individual hospitals. Mini-HTAs may also be initiated based on reports of technologies under development produced by the National Horizon Scanning process. In some cases proposals submitted for consideration at the national level may prove to be more suited to analysis at the local level through mini-HTAs.

[13] New EU regulations came into force on 25 May 2017. There is a transition period of 3 years for medical devices and 5 years for in vitro medical devices, respectively, before the regulations are fully in force (https://helsedirektoratet.no/medisinsk-utstyr/kommende-regelverk source).

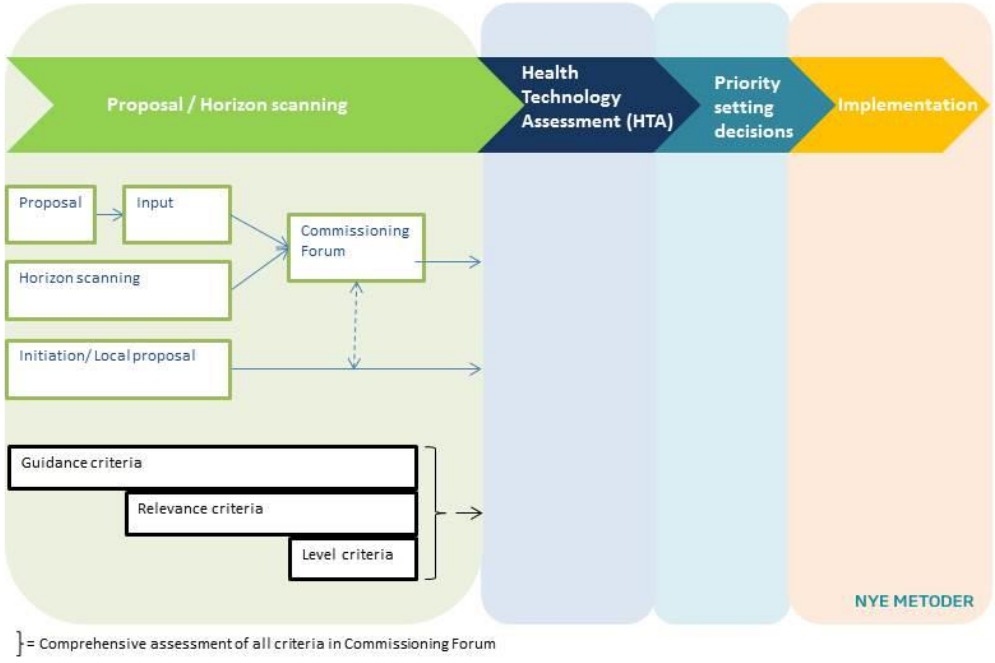
[14] Commissioning Forum assigns HTA tasks at the national level to the Norwegian Medicines Agency (Single Technology Assessments (STAs) for medicines) or the Norwegian Institute of Public Health (all full HTAs and STAs for medical devices).

[15] Commissioning Forum may assign tasks concerning HTAs of companion diagnostics in coordination with HTAs of medicines where this is seen as relevant

[16] http://www.helsebiblioteket.no/minimetodevurdering

Please see figure II, which illustrates where in the process through the system *Nye metoder* the different sets of guidance criteria are applicable.

Figure II – Process map for New Health Technologies and guideline criteria for medical devices:



The guidance criteria will be implemented in relevant contexts, i.e. published on the nyemetoder.no website, incorporated into relevant documents (proposal forms, input forms, the minimetodevurdering.no website, etc.), support case administration prior to and at the meetings of the Commissioning Forum, and so forth. After a certain time has elapsed, experiences from the guideline criteria will be evaluated with stakeholders and users (after approx. 1 year, or once a certain number of cases have been evaluated).

Dictionary

Commissioning Forum	Bestillerforum RHF
Decision Forum	Beslutningsforum for nye metoder
Regional Health Authorities (RHA)	Regionale helseforetak
The National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway	Nye metoder
National Procurement Organisation in Norway	Sykehusinnkjøp HF

Annex 1

In 2015, the system set up a working group to evaluate the handling of medical devices. The group consisted of representatives of stakeholders in *Nye metoder*, external partners and Norwegian Quality Improvement of Laboratory Examinations (NOKLUS), with its secretariat at the Norwegian Knowledge Centre for Health Services/Norwegian Institute of Public Health.

The major issues discussed were:

1. The need to clarify criteria as to which medical devices should be subject to HTAs, and channelling of HTAs to local or national levels
2. An option for the medical device industry to submit proposals for mini-HTAs
3. Establishing a cooperation with Norwegian Quality Improvement of Laboratory Examinations (NOKLUS)
4. Updating of the form and guidelines for mini-HTAs

A draft report was submitted to the Commissioning Forum on the 13th November 2015, circulated for input from *Nye metoder* reference group in November/December 2015 and forwarded to the Ministry of Health and Care Services on the 22th December 2015.

Nye metoder secretariat worked with the Regional Health Authorities (RHA) coordinators on following up individual proposals in the report and prepared case documents for the Commissioning Forum. The report was also sent to National Procurement Organisation in Norway (*Sykehusinnkjøp HF*). The final report from the working group was published at the Norwegian Institute of Public Health's website on the 12th October 2017 Link to report in Norwegian here

Item 4 above was discussed by the Commissioning Forum at a meeting on the 14th March 2016. Approval was granted for implementing pilot projects for mini-HTAs based on an updated form and guidelines.

Item 1 was further considered by the *Nye metoder* secretariat and the RHA coordinators, with input from stakeholders in *Nye metoder*, the reference group, the sectoral organisation for medical devices (Medtek Norge and LabNorge) and others.

On the 12th December 2016, the Commissioning Forum gave its approval to the guideline criteria for handling medical devices in *Nye metoder*. *Nye metoder* secretariat, in collaboration with the RHA coordinators, the Norwegian Institute of Public Health, and the trade organisations for medical devices, among others; then worked on how to present the guidance criteria in this document.

The present guidance document is a result of the above process and a final approvement from the Commissioning Forum on the 16th June 2017.

Annex 2

Medical devices (other) are divided into the following risk classes (Regulations of 15 December 2005 no. 1690 (concerning medical devices, Annex OMD IX Classification

criteria):

- Class I (low risk)
- Class IIa
- Class IIb
- Class III (high risk)

See the figure, page 9.
The classification reflects:

- the risk associated with use
- the vulnerability of the body parts on which the device will be used
- the duration of use

The highest class (III) includes products that come into contact with the central nervous system, the heart and the central circulatory system, as well as medical devices containing medicines. An example of a product in this class is a stent.

Further guidance is available in «MEDDEV 2.4/ Guidelines for classification of medical devices» (http://ec.europa.eu/growth/sectors/medical-devices/guidance_en).

For active implantable medical devices (AIMD), there is generally a high risk during use, and this group is not divided into risk classes. Examples of such products are pacemakers and cochlear implants.

In vitro diagnostic medical devices (IVDMD) are divided into the following groups (Regulations concerning medical devices, Annex IVDMD II Lists A and B of medical devices for in vitro diagnostics).

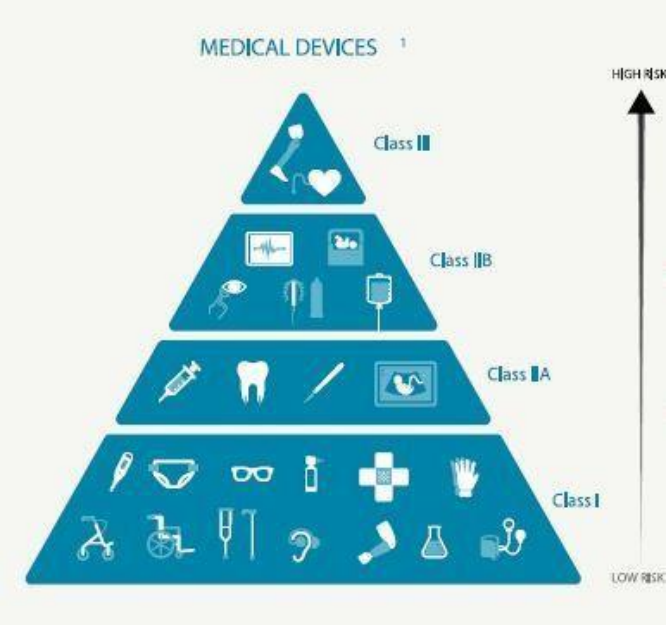
- List A
- List B
- Devices of self-diagnosis
- Other devices

National authorities and other competent authorities in the EU cooperate on classification decisions. In cases where the classification of a product as a medical device is not transparent, or where there is doubt about the risk classification of a medical device, the European medical device authorities will discuss the case amongst themselves.

A list of decisions is available in the “Manual on borderline and classification in the Community regulatory framework for medical devices”, which is updated continually (http://ec.europa.eu/growth/sectors/medical-devices/specific-areas-development_en).

Please see the illustrations below for examples of the types of medical devices included in the different risk classes. The illustration is taken from the report "The European Medical Technology Industry – in figures, MedTech Europe". Examples of what are included in Lists

A and B are taken from Lovdata (https://lovdata.no/dokument/SF/forskrift/2005-12-15-1690/KAPITTEL_9#KAPITTEL_9).



Attachment IVDMU II: List A and B of medical devices to in-vitro diagnostic referred to in § 3-2 (2) and § 3-3 (1) and (2)

List A

- Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: ABO system, rhesus (C, c, D, E, e) anti-Kell,
- Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D,
- Variant Creutzfeldt-Jakob disease (vCJD) assays for blood screening, diagnosis and confirmation.

List B

- Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: anti-Duffy and anti- Kidd,
- Reagents and reagent products, including related calibrators and control materials, for determining irregular anti-erythrocytic antibodies,
- Reagents and reagent products, including related calibrators and control materials, for the detection and quantification in human samples of the following congenital infections: rubella, toxoplasmosis,
- Reagents and reagent products, including related calibrators and control materials, for diagnosing the following hereditary disease: phenylketonuria,
- Reagents and reagent products, including related calibrators and control materials, for determining the following human infections: cytomegalovirus, chlamydia,
- Reagents and reagent products, including related calibrators and control materials, for determining the following HLA tissue groups: DR, A, B,
- Reagents and reagent products, including related calibrators and control materials, for determining the following tumoral marker: PSA,
- Reagents and reagent products, including related calibrators, control materials and software, designed specifically for evaluating the risk of trisomy 21,
- The following device for self-diagnosis, including its related calibrators and control materials: device for the measurement of blood sugar.